

Footnotes



Footnotes

1. Footnote 1. <http://www.cfsan.fda.gov/~dms/nuttf-e.html>
2. Footnote 2. The Osteoarthritis Initiative (OAI) is sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Health, Department of Health and Human Services (<http://www.niams.nih.gov/ne/oi/>)
3. Footnote 3. See <http://www.fda.gov/ohrms/dockets/ac/cfsan04.html> for FAC transcripts and other meeting information.
4. Footnote 5. Eburnation is a change in exposed subchondral bone in degenerative joint disease in which subchondral bone is converted into a dense substance with a smooth surface like ivory (Stedman's Medical Dictionary).
5. Footnote 6. An osteophyte is a bony outgrowth or protuberance (Stedman's Medical Dictionary).
6. Footnote 7. <http://www.rheumatology.org/public/factsheets/oa.asp?aud=pat>
7. Footnote 8. <http://www.clinicaltrials.gov/show/NCT00032890>
8. Footnote 9. <http://clinicaltrials.gov/show/NCT00086229>
9. Footnote 10. <http://ntp-server.niehs.nih.gov/NomPage/2003Noms.html>
10. Footnote 11. Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, December 22, 1999. <http://www.cfsan.fda.gov/~dms/ssaguide.html>
11. Footnote 23. A chondrocyte is a non-dividing cartilage cell occupying a lacuna (i.e., small space or cavity) within the cartilage matrix (Stedman's Medical Dictionary).
12. Footnote 27. A cytokine is a generic term for nonantibody proteins released by one cell population on contact with specific antigen, which act as intercellular mediators, as in the generation of an immune response (Dorland's Illustrated Medical Dictionary).
13. Footnote 36. An observational study records specific events that are occurring in a defined population without any intervention by the researcher (Spilker, 1991, p. 47).
14. Footnote 41. A meta-analysis is the process of systematically combining and evaluating the results of clinical trials that have been completed or terminated (i.e., primary reports) (Spilker, 1991, p. 793). FDA uses meta-analysis to identify relevant primary reports, which the Agency then evaluates.
15. Footnote 44. The background section of the FAC questions document (http://www.fda.gov/ohrms/dockets/ac/04/briefing/4045b1_06_a_Questions%20Revised.pdf) stated that FDA also refers to modifiable risk factors/surrogate endpoints for disease as "biomarkers" and further explained, in part, that a biomarker is "a measurement of a variable related to a disease that may serve as an indicator or predictor of that disease. Biomarkers are parameters from which the presence or risk of a disease can be inferred, rather than being a measure of the disease itself. In conducting a health claim review, FDA does not rely on a change in a biomarker as a measurement of the effect of a dietary factor on a disease unless there is evidence that altering the parameter can affect the risk of developing that disease or health-related condition." See also the discussion of modifiable risk factors in the introduction to section II.
16. Footnote 45. <http://www.cfsan.fda.gov/~dms/ds-ltr11.html>